

Considering The Status Of The US Doctrine Of Patent Misuse

By **Inga Pietsch and Winsome Cheung** (January 16, 2025, 3:02 PM EST)

Ten years have passed since the U.S. Supreme Court's 2015 decision in *Kimble v. Marvel Entertainment LLC*, which affirmed the principle established in *Brulotte v. Thys* in 1964, that payment of post-patent-expiration royalty payments amounts to patent misuse under the U.S. patent misuse doctrine.

The doctrine of patent misuse is multifaceted and has been applied in many cases, most recently in the case of *CR Bard Inc. v. Atrium* last year, where the U.S. Court of Appeals for the Ninth Circuit rejected an allegation of patent misuse by the defendant, Atrium. This article provides an overview of this principle as established by *Brulotte*, and explores the evolution in the U.S. courts' approach in *Kimble* and *Bard*.

This article also explores the extent to which the English courts are willing to take the doctrine of patent misuse into account when interpreting English law licenses, in particular by considering the U.K. Court of Appeal's decision in *AstraZeneca UK Ltd. v Tesaro Inc.* last year.

Introduction

The key principle of the U.S. doctrine of patent misuse is to prevent a patentee from seeking to extend the monopoly of its patent beyond the patent's legally allowed scope, in order to protect the market.

It is an affirmative defense that may be raised in response to a suit for patent infringement, or in the context of a dispute over a patent license. Acts comprising patent misuse in connection with disputes over patent licenses may include a continuing obligation to pay royalties after expiration of a patent, or for unpatented products, or tying arrangements in which the patentee requires the licensee to obtain unpatented products from it.

The doctrine of patent misuse has long historical roots, with its origins in equity, but has subsequently been mixed in with concepts of anticompetitive behavior by the patentee.

Over the years, the instances that may give rise to patent misuse have been refined. In addition to the concept of patent misuse *per se*, variations have developed in which a showing of anticompetitive behavior or impact may be required to be made in addition to an attempt to enforce the patent outside of its legally allowed scope.



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The U.S. doctrine of patent misuse continues to be a shield that defendants look to rely upon in patent disputes as evidenced by the recent Atrium case.

There is no English law doctrine that is directly equivalent to patent misuse. However, licensing arrangements often involve a global bundle of intellectual property rights — and thus affect global markets, including the U.S.

It therefore triggers a question as to whether the English courts might take into consideration the U.S. patent misuse doctrine when interpreting licensing agreements under English law.

This article examines the extent to which parties to licenses governed by English law need to be mindful of the patent misuse doctrine and the impact it has on the construction of licensing terms, based on the AstraZeneca case.

Royalty Payments Beyond the Expiration of the Patents

Of key relevance to licensing lawyers is the unlawfulness of royalty payment obligations after patent expiration.

The principle was established in *Brulotte*, a case that concerned a patent license relating to hop-picking machines, where royalty payments on the use of the machines were due even after the relevant patents had expired. The U.S. Supreme Court held that "a patentee's use of a royalty agreement that projects beyond the expiration date of the patent is unlawful per se."

The *Brulotte* decision has attracted mixed reactions over time, as some consider that it fetters the ability of the parties to structure a commercial bargain.

The matter of post-patent royalty obligations reached the Supreme Court again in 2015 in the *Kimble* case.

The Supreme Court affirmed the *Brulotte* principle that post-patent royalty payments were unlawful. However, the Supreme Court provided suggestions on how parties may work around this principle.

For example, basing any post-patent royalty payments on licensed nonpatent IP rights, such as know-how, or structuring royalty payments as deferred payments or lump sum payments may avoid application of the *Brulotte* principle.

A customary approach in structuring an IP license post-*Kimble* is to provide for a royalty step-down following patent expiration, with any post-patent royalty payments intended to reflect the remaining value of the licensed nonpatent IP.

The *Brulotte* decision was recently considered in *Atrium*. The parties had agreed on a 15% per-unit royalty on U.S. and Canadian sales of the licensed products until the expiration of the corresponding patents in 2019 and 2024 respectively. The parties had also agreed that Atrium must pay Bard a \$15 million annual royalty payment during the term.[1]

However, one product covered by the patents and sold by Atrium in the U.S. was initially not subject to the per-unit royalty, as approval from the U.S. Food and Drug Administration was still pending. The

product was in fact used off-label for an unapproved indication and an aspect of the minimum royalty payment was to take account of such sales.

The parties agreed that once FDA approval was granted, the product would become subject to the 15% per-unit royalty, and the minimum royalty payments would terminate. However, FDA approval was not granted until 2023, after the U.S. patents had expired.

Atrium ceased making the minimum royalty payments when the U.S. patents expired in 2019, but while the Canadian patents were still in force. Bard sued for the outstanding payments and Atrium argued that such post-patent payment obligations were invalid under *Brulotte*.

In addition, Atrium argued that it made little to no sales in Canada, and that the royalty payments generated by these sales were much smaller than the minimum royalty payment.

Although at first instance the U.S. District Court for the District of Arizona held that the obligation to make the minimum royalty payment after expiration of the U.S. patents amounted to patent misuse, the Ninth Circuit reversed the decision.

The Ninth Circuit held that *Brulotte* is to be applied without a formal inquiry into the consideration of the motivation, "the course of their negotiations, or the consideration received by either party in exchange for the inclusion of a particular contractual term."

Once the terms of the contract have been construed, the only question that arises in assessing *Brulotte* is whether royalty payments are due on U.S. patents after their expiration date. In this license, they were not.

The Ninth Circuit found that the royalty payments on the U.S. patents ceased on the expiration of the U.S. patent. However, the minimum royalty payment provided for a minimum amount to be paid for the use of all unexpired patents in their respective countries "until the last to expire of all of the patents included within the Licensed Patents."

In this case, the only patent that had not expired was the Canadian patent. For this reason, there was no patent misuse.

Interestingly, the Ninth Circuit refused to consider the parties' motivation and the course of their negotiations on which the first instance court had relied in its finding of patent misuse.

The Ninth Circuit emphasized that, according to the Supreme Court's decision in *Kimble*, parties are free to find ways around the patent misuse per se rule for post patent expiration royalty payments, and a consideration of the parties' motivation would conflict with this principle.

This case further demonstrates the leeway parties have to seek alternative financial models involving payments after patent expiration. Atrium filed a petition for a rehearing that was denied.

Consideration for Life Sciences Transactions

Especially in life sciences where the research and development pathway can take years, commercialization of the product often occurs close to patent expiration.

Accordingly, if the patentee can only receive royalties on product sales for the duration of the patent life, the patentee may only be able to exploit its IP during a period when the patents are in force for only a short period of time, if at all.

As such, the patentee typically wishes to shift some of the monetary reward from the licensee until a time following patent expiration. Licensing lawyers therefore must carefully consider the impact and structure of the royalty provisions, in particular in the case of patent portfolios that include U.S. patents.

Whether the Brulotte and Kimble principles would apply to post-patent royalties for U.S. patents under English law agreements has not been specifically tested in English courts.

However, there is one recent U.K. case concerning a licensing dispute at the English courts in which the court sought evidence from U.S. lawyers on the doctrine of patent misuse to aid the court in construing the terms of a license agreement governed by English law.

Total Sales Royalties

In AstraZeneca, the English court was tasked with construing certain royalty provisions in license agreements entered into between AstraZeneca and Tesaro, the sublicensor and sublicensee respectively.

The license agreement granted rights to the licensed patents. The licensed patents were second medical use patents and therefore did not protect the relevant PARP, or poly (ADP-ribose) polymerase, inhibitors as such, but instead covered the use of a range of PARP inhibitors in certain treatment regimes.

According to the license agreement, Tesaro had to pay royalties in respect of each licensed product on a country-by-country basis and the obligation to pay a royalty on sales in a particular country commenced only when a patent was granted in that country that "covers or claims the Exploitation of the Licensed Product."

The licensed products were defined as "the Product and the Combination Product" and the product was in turn defined as "any product in a form suitable for human applications that contains the Compound as the sole active ingredient."

The obligation to pay a royalty in a particular country ceased once there was no longer a valid and enforceable patent that "covers or claims the Exploitation of the Licensed Product in such country."

The critical language was in the definition of "Compound," which was defined as "PARP inhibitor compounds niraparib and Mk-2512 the use of which may be claimed or covered by, or the Exploitation of which may be claimed or covered by, one or more of the Licensed Patents."

The question arose regarding whether the phrase "may be" meant that royalty payments were to be made on all sales of the product, including for uses not covered by the licensed patents, or only based on sales of the product for uses claimed or covered by the licensed patents as defined within the license agreements.

Tesaro argued the latter, which AstraZeneca disputed.

Applying the usual rules of contractual interpretation under English law — given that no special rules of

interpretation apply to patent licenses — the first instance judge, Justice Richard Arnold, was required to:

identify the intention of the parties by reference to what a reasonable person having all the background knowledge which would have been available to the parties would have understood them to be using the language in the contract to mean. That meaning has to be assessed in the light of (i) the natural and ordinary meaning of the clause, (ii) any other relevant provisions of the contract, (iii) the overall purpose of the clause and the contract, (iv) the facts and circumstances known or assumed by the parties at the time that the document was executed, and (v) commercial common sense, but (vi) disregarding subjective evidence of any party's intentions.[2]

The parties agreed that the doctrine of patent misuse had some relevance to the construction of the license agreements involved, because the patents subject to the licenses included U.S. patents, and the U.S. was a major market for both AstraZeneca and Tesaro. This formed part of the factual matrix against which the construction of the terms was to be considered.

Having listened to expert evidence on the U.S. doctrine of patent misuse, Justice Arnold concluded that although the factual matrix provided some indication that "the parties would not have wished to agree a total sales royalty because of the risk of patent misuse," this consideration was "not sufficient to displace the inferences to be drawn from the ordinary language of the Licence Agreement."

He found in favor of AstraZeneca and held that Tesaro was obliged to pay AstraZeneca royalties on all net sales of the product in each country in which there are licensed patents from the first commercial sale in that country.

Tesaro appealed. The Court of Appeal reversed the first instance decision and allowed Tesaro's appeal. The Court of Appeal gave multiple reasons for its decision, one such reason being a potential risk of falling foul of the U.S. doctrine of patent misuse, which appeared to be weighted in favor of a construction against a total sales royalty.

In particular, Justice Arnold stated at Paragraph 36 that

Sixthly, it is a well-established principle of interpretation that, where the words of a contract are capable of two meanings, one of which is lawful and the other unlawful, the former interpretation is to be preferred: see Lewison, *The Interpretation of Contracts* (8th ed) at 7.119-7.125. On Tesaro's interpretation the Licence Agreements do not contravene the US patent misuse doctrine, whereas on AZ's interpretation there is a serious risk that they would do so given that they do not contain any statement to the effect that the scope of the royalty obligation has been framed for the mutual convenience of the parties, nor is there any evidence that mutual convenience was the reason for the adoption of the italicised words. The judge accepted that this was a factor which favoured Tesaro's interpretation, but concluded that it was insufficient to displace his interpretation of the wording in question.

Both Justice Colin Birss and Justice Eleanor King concurred that the risk of the patent misuse doctrine coming into play was a particularly important point favoring an interpretation that a total sales royalty should not apply.

Conclusion

Each case will naturally turn on its facts. However, what the AstraZeneca case has demonstrated is that

the U.K. court is willing to take the U.S. doctrine of patent misuse into account to aid in the construction of English law licenses, where it may be an aspect, as in this case, relevant to the factual matrix.

Importantly, as the Court of Appeal has recognized, it may be relevant to weighing in favor of a construction where one is lawful and the other unlawful.

This does not mean that a total sales royalty, under English law, is unlawful per se. However, if there is ambiguity in the wording, and if the U.S. market or patents are of relevance, then the U.S. law doctrine of patent misuse may be more seriously considered in the construction of a patent license than the parties had originally anticipated.

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[1] The agreement provided: "in no event will royalties for any calendar quarter of the Term be less than" \$3.75 million" (equivalent to \$15 million per year). The Term was defined as "...until the last to expire of all the patents included within the Licensed Patents, unless earlier terminated in accordance with its terms."

[2] Carr LJ in ABC Electrification Ltd v. Network Rail Infrastructure Ltd [2020] EWCA Civ 1645.